Exhibit 19 Summary of Safety & Effectiveness

K030061

APR 0 7 2003

19 December 2002

The ***PS 3000 Digital PhotoSpot System*** [tm], Picture archiving and communications system is designed for clinical applications to allow health care providers to acquire, record, display and publish diagnostic images. As such, ***this device*** is a Class II device, having Regulation Number: ***21 CFR part*** ~~***892.2050***~~, Classification Number: ~~LLZ~~ JAA, OWB 892.1650

This summary is submitted in behalf of:
Precise Optics/PME, Inc.
239 South Fehr Way,
Bay Shore NY 11706
Voice phone number-631 242 6600
Fax phone number- 631 242 4421

This summary is submitted by:
Richard Keen
Compliance Consultants
1151 Hope Street
Stamford, Connecticut, 06907
voice phone number (203) 329 2700)
fax phone number (203) 329 2345.

This device can be **described** as a Class II diagnostic system that receives an image from an image intensifier tube and acquire, record, display and publish diagnostic images using proprietary techniques. This device is composed of:

- software {that runs in a qualified, ancillary computer},
- proprietary hardware and software, and a
- CCD Camera that receives the image.

All ancillary equipment, which works with this device, is identified as a configured item and tested to formal procedures. This device will only be used with specific ancillary equipment, which is tested and qualified to work with ***PS 3000 Digital PhotoSpot System*** [tm].

The **scientific concept** on which this device is based that by monitoring images from the image intensified tube a valid diagnostic image can be derived and reproduced.

This device **functions** by converting an optical (analog) image to a digital image having sufficient diagnostic properties as to assist the physician in establishing a diagnosis.

The **intended use** of this device is for a trained health care professional to produce a diagnostic image. The ***PS 3000 Digital PhotoSpot System*** [tm] uses sophisticated digital signal processing and data collection/display techniques to offer the physician or trained health care provider, a reliable, simple tool.

The ***PS 3000 Digital PhotoSpot System*** [tm] is a high resolution, digital imaging system designed for Digital Videography. It is intended to replace conventional film techniques in multipurpose or dedicated applications where general fluoroscopy, interventional fluoroscopy and angiography or cardiac imaging procedures are performed.

The ***PS 3000 Digital PhotoSpot System*** [tm] is indicated for use when it is necessary for a trained health care professional (for example an Radiologist) to acquire, record, review and distribute a digital image from a x-ray image intensifiers in diagnostic imaging chains.

Exhibit 19 Summary of Safety & Effectiveness

The ***PS 3000 Digital PhotoSpot System*** ™ is a prescription device. The labeling, instructions and user operations are designed for trained professionals.

Precise Optics/PME, Inc. has determined that the ***PS 3000 Digital PhotoSpot System*** ™ is substantially equivalent to the performance of a an existing medical device:

Patriot, now ***Gold One,*** manufactured by Infimed, Inc. of Liverpool, NY13088 (K963037). The differences between these systems are incidental and not significant. Both devices use a similar technology and principles.

Precise Optics/PME, Inc. has determined that *this device* is substantially equivalent to the predicate device and has these similar technological characteristics:

both devices use computers and software having analog/digital processing,
both devices produce diagnostic images, and
both use computer processing to acquire, store, display and publish diagnose images.

A series of factory adjustments/calibration tests are conducted to verify the device is accurate can maintain calibration over its useful life. The ***PS 3000 Digital PhotoSpot System*** ™ has benefited from design, development, testing and production procedures that conform to Quality Systems.

This device is safe and effective for the application for which it is intended and has been tested to confirm safety and efficacy. ***Precise Optics/PME, Inc.*** continues to research all appropriate sources for information relating to safety and effectiveness and maintains an *in-house* reporting system to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

CERTIFICATION:
I hereby certify this **Summary of Safety and Effectiveness** applies for the above indicated device.

Mr. Glen Corso
President
Precise Optics/PME, Inc.
239 South Fehr Way,
Bay Shore NY 11706
Voice 631 242 6600
Fax 631 242 4421

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAY - 7 2012

Precise Optics/PME, Inc.
% Mr. Richard Keen
Compliance Consultants
1151 Hope St.
STAMFORD CT 06907

Re: K030061
Trade/Device Name: PS 3000 Digital Photospot System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: December 19, 2002
Received: January 7, 2003

Dear Mr. Keen:

This letter corrects our substantially equivalent letter of April 7, 2003.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Exhibit 2

510(K) Number (If known): K030061 **no 510(K) number assigned**__
Device Name: __ ***PS 3000 Digital PhotoSpot System*** ™

Indications for Use

The ***PS 3000 Digital PhotoSpot System*** ™ is a high resolution, digital imaging system designed for Digital Videography. It is intended to replace conventional film techniques in multipurpose or dedicated applications where general fluoroscopy, interventional fluoroscopy and angiography or cardiac imaging procedures are performed.

The ***PS 3000 Digital PhotoSpot System*** ™ is indicated for use when it is necessary for a trained health care professional (for example an Radiologist) to acquire, record, review and distribute a digital image from a x-ray image intensifiers in diagnostic imaging chains.

The ***PS 3000 Digital PhotoSpot System*** ™ is a prescription device. The labeling, instructions and user operations are designed for trained professionals.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K030061

Prescription Use ✓ _____
(Per 21 CFR 801.109)

or Over - The - Counter Use ___XXX_____

(Optional Format 1-2-96)